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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LAZAR WESLEY, ELIANE M

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/475,158

Applicant(s)

Gardella

Examiner

Eliane Lazar-Wesley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 6, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-40 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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### DETAILED ACTION

Applicants request for a new restriction requirement including the details of how claim 1 is a linking claim is acknowledged and granted. The original groups of II through XXI have been restructured as a through u to more clearly delineate how they are linked to claim 1. The restriction requirement has also been restructured to more clearly point out other linking or generic claims and the relationships between them. Presumably applicant maintains the election of Group I in Paper No. 13 filed 2/07/02. Applicant is required to further elect a single invention of groups a through u for examination at this time as detailed below in the explanation of the function of claim 1 as a linking claim serving to link several distinct inventions.

Group I        Claims 1-14, and 37, to a polypeptide of formula S-L-B, where

S = amino terminal signal domain of PTH,

L = linker,

B = C-terminal binding portion of either PTH or PTHrP.

Group II       Claim 15, to a nucleic acid encoding a polypeptide of the formula S-L-B.

Group III      Claims 16-18, to a polypeptide of formula R1-S-L-R wherein

R1 = PTH-1 receptor sequence,

S = amino terminal ligand signaling peptide,

L = linker

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R = PTH-1 receptor sequence.

Group IV Claim 19, to a nucleic acid encoding a polypeptide of formula R1-S-L-R.

Group V Claims 20-22, to a polypeptide of formula S-R wherein

S = amino terminal signaling polypeptide

R = C-terminal receptor polypeptide.

Group VI Claims 23-29, to a nucleic acid encoding a polypeptide of the formula S-R.

Group VII Claims 30 and 32-34, to a method of increasing bone mass by administering the polypeptide of Group I.

Group VIII Claims 30 and 32 - 34, to a method of increasing bone mass by administering a polypeptide of Group III

Group IX Claims 30 and 32 -34, to a method of increasing bone mass by administering a polypeptide of Group V.

Group X Claim 31, to a method of detecting bone resorption using a polypeptide of Group I.

Group XI Claim 31, to a method of detecting bone resorption using a peptide of Group V.

Group XII Claim 31, to a method of detecting bone resorption using an agonist of PTH.

Group XIII Claims 35 and 36, to a method of decreasing Tether1 activity by administering a peptide of Group I

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Group XIV    Claims 35 and 36, to a method of decreasing Tether1 activity by administering a peptide of Group III.

Group XV    Claims 35 and 36, to a method of decreasing Tether 1 activity by administering an agonist.

Group XVI    Claims 38 and 39, to a method of screening for an agonist

Group XVII    Claim 40, to an agonist.

The inventions of Groups I and II differ in that they are drawn to entirely different products having different chemical structures and different biological functions and uses. While the polypeptides may be made by expressing the nucleic acids of Group II, it may also be chemically synthesized.

The inventions of Groups I and III are drawn to entirely different generic peptide constructs having different required elements. The peptide construct of Group I does not require any sequence from the PTH -1 receptor molecule as does the peptide construct of Group III, therefore resulting in non-cohesive searches.

Similar to the inventions of Groups I and II, the inventions of Groups III and IV differ in that they are drawn to entirely different products having different chemical structures and different biological functions and uses. While the peptides may be made by

the nucleic acids of Group IV, they may also be chemically synthesized

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The invention of Group V differs from that of Groups I and III, being drawn to another entirely different peptide construct requiring different considerations and searches from those required for Groups I and III.

Similar to the inventions of Groups I and II, and III and IV, the inventions of Groups V and VI differ in that they are drawn to entirely different products having different chemical structures and different biological functions and uses. While the peptides may be made by expressing the nucleic acids of Group VI, they may also be chemically synthesized.

The inventions of Groups VII, VIII, and IX are drawn to methods of increasing bone mass by administering peptide constructs that are entirely different as indicated by their restriction to Groups I, III, and V. Therefore, the methods of increasing bone mass are similarly restricted into three different methods of invention because each method requires a completely different method composition that is not required for the other and necessitates a non-cohesive search and consideration. The inventions of Groups VII, VIII, and IX are related to the inventions of Groups I, III, and V as a product and process of use, however, they may be shown to be distinct as the product may be used in a materially different method such as to detect bone resorption or to raise antibodies while the methods may clearly also be practiced using distinct products.

Similar to the inventions of Groups VII, VIII, and IX, the methods of Groups X, XI, and XII are drawn to entirely different methods requiring entirely different method compositions that require different searches and considerations. Also, the inventions of

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Groups X, XI, and XII are related to the inventions of Groups I, III, and XVII as products and processes of use which can be shown to be distinct if the the products may be used in a materially different manner, which in this case is true, the products may be used to increase bone or to raise antibodies. Also, the methods may be practiced using distinct products.

Similar to the inventions of Groups X, XI, and XII, the inventions of Groups XIII, XIV, and XV are drawn to entirely different methods requiring entirely different method compositions that require different searches and considerations. Also, the inventions of Groups XIII, XIV, and XV are related to the inventions of Groups I, III, and XVII as products and processes of use which can be shown to be distinct if the the products may be used in a materially different manner, which in this case is true, the products may be used to detect bone resorption or to raise antibodies. Also, the methods may be practiced using distinct products.

The method of Group XVI differs from any of the methods of Groups X to XV, having completely different method steps and method outcomes. None of the methods of Groups X to XV result in the identification of an agonist of PTH.

Finally, the invention of Group XVII is related to the method of Group XVI as a product and method of making but is distinct because the product may be made in a materially different manner, such as by chemical synthesis. Furthermore, the product differs from those of Groups I, III, and V having different properties and not requiring the structural

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features of any of the products of Groups I, III, and V, thus requiring non-cohesive searches and considerations.

Claim 1 of Group I serves as a linking claim for several distinct products which would ordinarily result in restriction to different groups of invention. The distinct products are:

- a. SEQ ID NO: 3
- b. SEQ ID NO: 5
- c. SEQ ID NO: 6
- d. SEQ ID NO: 9
- e. SEQ ID NO: 11
- f. SEQ ID NO: 13
- g. SEQ ID NO: 14
- h. SEQ ID NO: 15
- i. SEQ ID NO: 16
- j. SEQ ID NO: 42
- k. SEQ ID NO: 44
- l. SEQ ID NO: 64
- m. SEQ ID NO: 65
- n. SEQ ID NO: 66
- o. Peptides in which S is SEQ ID NO: 1
- p. Peptides in which S is SEQ ID NO: 4
- q. Peptides in which S is SEQ ID NO: 67
- r. Peptides in which B is SEQ ID NO: 2



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- s. Peptides in which B is SEQ ID NO: 63
- t. Peptides in which B is SEQ ID NO: 8
- u. Peptides in which B is SEQ ID NO: 12

Each of these peptides of groups a through u are entirely different products with different structures and requiring different searches and considerations, each of which is not required for any other. They are linked by the generic formula of claim 1. Applicant is required to elect a single invention of groups a through u which will be examined along with the generic linking claim 1 should applicant elect Group I. This restriction requirement is subject to the nonallowance of the linking claim 1. Upon allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. Likewise, the nucleic acids of Group II are subject to similar restriction requirements to nucleic acids encoding each of groups a through u

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Similarly, Claim 20 of Group V serves as a linking claim for several distinct products which would ordinarily result in restriction to different groups of invention. The distinct products are:

- a. SEQ ID NO: 37
- b. SEQ ID NO: 39
- c. SEQ ID NO: 41

Each of these peptides are entirely different products with different structures and requiring different searches and considerations, each of which is not required for any other. They are linked by the generic formula of claim 20. Applicant is required to elect a single invention of groups a through c which will be examined along with the generic linking claim V should applicant elect Group V. This restriction requirement is subject to the nonallowance of the linking claim 20. Upon allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the

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provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. Likewise, the nucleic acids of Group VI are subject to similar restriction requirements to nucleic acids comprising SEQ ID NO: 36, 38 or 40.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW  
April 19, 2002

EW

  
YVONNE EYLER, PH.D.  
SENIOR PATENT EXAMINER